FDA Risk Communication Advisory Committee The Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD February 25-26, 2010 AGENDA

February 25, 2010

- 8:00 Call to Order
- 8:05 Conflict of Interest Statement Designated Federal Officer
- 8:10 Introductions of Committee Members
- 8:30 FDA Welcome

Nancy M. Ostrove, Ph.D., Director for Risk Communication

- **8:45 Communication Challenge:** FDA seeks to ensure that healthcare professionals know about new or updated safety information about a product and carefully monitor their patients who use the product. At the same time, FDA also wants to ensure that relevant patients know about the safety information and that FDA is addressing the issue. However, FDA does not want to cause undue alarm.
- 10:15 Break
- 10:30 Further Committee Discussion
- **12:00** Lunch (on your own)
- 1:00 Open Public Hearing
- **2:00 Communication Challenge:** FDA seeks to ensure that all product users know about new or updated safety-related information and understand what both healthcare professionals and patients or caregivers should do about the new information.
- 3:15 Break
- **3:30 Communication Challenge:** FDA seeks to ensure that healthcare professionals and the public know about an ongoing investigation, where those affected by the risk may be of special concern to the population at large.
- 5:00 Adjourn for the day

FDA Risk Communication Advisory Committee The Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD February 25-26, 2010 AGENDA

February 26, 2010

- 8:00 Call to Order and Conflict of Interest Statement
- 8:05 Introductions of Committee Members
- 8:10 Welcome

Nancy M. Ostrove, Ph.D., Director for Risk Communication

- **8:15 Communication Challenge:** FDA seeks to ensure that healthcare professionals and the public know about how to use a product appropriately in a crisis or emergency situation where the regulatory status of the product is a key factor in understanding appropriate use.
- **9:15 Communication Challenge:** FDA seeks to inform a broad and diverse public by reaching out through multiple channels.
- 10:15 Break
- 10:30 Open Public Hearing
- 11:30 Lunch (on your own)
- 12:30 Final Committee Discussion
- 2:00 Adjourn